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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David John Haydon

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WILSON, SONSINI, GOODRICH & ROSATI
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EXAMINER

CHOWDHURY, IQBAL HOSSAIN

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

11/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,756	Applicant(s) HAYDON, DAVID JOHN	
	Examiner IQBAL H. CHOWDHURY	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 11, 14-16 and 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-10, 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

Claims 1-11 and 14-22 are currently pending.

In response to a previous Office action, a non-final action (mailed on April 13, 2009), Applicants filed a response and amendment on July 13, 2009, amending claims 9-10 and 17 is acknowledged. Claims 1-8, 11, 14-16 and 18-22 remain withdrawn. Claims 9-10 and 17 are under consideration.

Applicants' arguments filed on July 13, 2009, have been fully considered but are not deemed persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Maintained-Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The previous rejection of claims 9-10 and 17 under 35 U.S.C. 102(b) as being anticipated by Miyazaki et al. (Comparison of kinetic properties between MSS4 and Rab3A GRF GDP/GTP exchange proteins, FEBS Lett, 1994 Aug 22;350(2-3):333-6) is maintained. This rejection has been discussed at length in the previous office action. The rejection is maintained as discussed previously and for the following reasons.

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The instant claims are drawn to a compound, which impairs fungal 1-phosphatidylinositol-4-phosphate 5-kinase (MSS4) function.

Miyazaki et al. teach RabGD1, which is inhibitory of GEP (GDP/GTP exchange protein) inhibits MSS4 (abstract, line 4, page 335, column 1, paragraph 2 and Fig. 4), wherein the assay method comprises contacting RabGD1 with MSS4 (page 334, column 1, paragraph 3), wherein said compound would have inhibitory activity to any MSS4 including fungal MSS4. A composition (claim 10) comprising inhibitor of MSS4 is nothing but the inhibitor of MSS4 itself and a pharmaceutically acceptable carrier can be water or buffer which is taught by Miyazaki et al.

While claims 9 and 17 recite products in product by process form, patentability of a product by process claim is determined by the characteristics of the product only. As there is no evidence that the inhibitor product as recited in claims 9 and 17 would be any different from the inhibitor recited by the prior art.

Because the compound of the claimed invention and the corresponding compound of the reference is identical, Examiner takes the position that the compound of the reference inherently have inhibitory to fungal MSS4. Since the Office does not have the facilities for examining and comparing applicants' compound with the compound of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Arguments/Response

Applicants argue that *Miyazaki et al.* do not teach the recited steps of identifying a fungal MSS4 compound as recited by claims 9, 10, and 17. In fact, *Miyazaki et al.* do not teach contacting fungal MSS4 with the Examiner's alleged MSS4 inhibitor (i.e., RabGD1). Rather, *Miyazaki et al.* disclose the dissociation of [3H]GDP from the small G protein to be tested was assayed by measuring the radioactivity of [3H]GDP bound to the small G protein after incubation with MSS4, Rab3AGRF, or Rab GDI. Thus, contrary to the assertion by the Examiner, *Miyazaki et al.* do not teach at least the step of contacting fungal MSS4 with one or more candidate compounds.

This is not found persuasive because claims are product claim (Product by process), since, the product is taught by the *Miyazaki et al.*, the process of identification is not given patentable weight because patentability of a product by process claim is determined by the characteristics of the product only. Besides, *Miyazaki et al.* indeed teach contacting MSS4 with Rab GDI because the assay format is incubation of MSS4, Rab3A GRF or Rab GDI in a tube, wherein each of the components is in contact with each other. Thus, contrary to applicants arguments, *Miyazaki et al.* indeed teach RabGD1, which is inhibitory of GEP (GDP/GTP exchange protein) inhibits MSS4 (abstract, line 4, page 335, column 1, paragraph 2 and Fig. 4), wherein the assay method comprises contacting RabGD1 with MSS4.

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Applicants also argue that the Examiner does not appear to dispute that *Miyazaki et al.* do not disclose candidate compounds have impair MSS4 function as recited in claims 9, 10 and 17.

This is not found persuasive because Miyazaki et al. indeed teach that Rab GDI inhibits MSS4 function (see abstract) and furthermore, Rab GDI inhibits GDP-exchange function of MSS4 (see Fig. 4A). Thus, the impairment of MSS4 function is the inhibition of the MSS4 function. Besides, claims are product in product by process form, patentability of a product by process claim is determined by the characteristics of the product only. As there is no evidence that the inhibitor product as recited in claims 9 and 17 would be any different from the inhibitor recited by the prior art.

Applicants further argue that Miyazaki et al. do not Inherently Anticipate Claims 9, 10, and 17 and further argue that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic and the inherency [may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. Miyazaki et al. do not inherently disclose an inhibitor of fungal MSS4.

This is not found persuasive because applicants claim compound, which inhibits MSS4 of fungal origin, and Miyazaki et al. teach a compound which inhibits MSS4 of rat origin, i.e. there is no evidence that compound of Miyazaki et al. would not inhibit MSS4 of fungal origin.

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Furthermore, applicants argue that according to Miyazaki et al., "Rab GDI slightly inhibited the Rab3A GRF effect on the lipid-unmodified form of Rab3A, but did not affect the MSS4 effect on the same form of Rab3A." Miyazaki et al, page 335, column 1, paragraph 2 (section 3, Results). Thus, the Examiner's alleged MSS4 inhibitor (i.e., Rab GDI) does not inevitably and always inhibit rat brain MSS4 function. See, e.g., *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343-44 (Fed. Cir. 2005) (requiring the "inevitably and always" standard for inherent anticipation).

This is not found persuasive because Miyazaki et al. indeed teach that Rab GDI inhibits MSS4 function (see abstract) and furthermore, Rab GDI inhibits GDP-exchange function of MSS4 (p335, Col 1, paragraph 2, line 4-6 and Fig. 4A) in a lipid modified form. It is untrue that Rab GDI does not always inhibit rat brain MSS4 function, where lipid modified or lipid unmodified is the conditions of the assay and Rab GDI indeed inhibits MSS4 in lipid modified condition (p335, Col 1, paragraph 2, line 4-6 and Fig. 4A). Besides, the facts pattern of *SmithKline Beecham Corp. v. Apotex Corp* is different from the facts pattern of the instant application, which cannot be compared with the instant application.

Therefore, the rejection is maintained.

Conclusion

Status of the claims:

Claims 1-11 and 14-22 are pending.

Claims 1-8, 11, 14-16 and 18-22 are withdrawn.

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Claims 9-10 and 17 are rejected.

No claims are allowed.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Iqbal Chowdhury, Patent Examiner
Art Unit 1652

/Richard G Hutson/
Primary Examiner, Art Unit 1652